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COMMISSION

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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the authorisation of a preparation of *Enterococcus lactis* NCIMB 11181 as a feed additive for poultry for fattening and reared for laying or reproduction and ornamental birds (holder of authorisation: Chr. Hansen A/S)

(Text with EEA relevance)

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition[1], and in particular Article 9(2) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such an authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of a preparation of *Enterococcus lactis* NCIMB 11181. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of the preparation of *Enterococcus lactis* NCIMB 11181 as a feed additive for use in feed and in water for drinking for chickens for fattening or reared for laying, other poultry species for fattening or reared for laying, and ornamental birds, requesting the simultaneous use of that preparation in feed with the coccidiostats monensin sodium and decoquinate, and for that additive to be classified in the category 'zootechnical additives' and in the functional group 'gut flora stabilisers'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 30 January 2024[2] that the preparation of *Enterococcus lactis* NCIMB 11181 is safe for chickens for fattening or reared for laying, other poultry species for fattening or reared for laying, and ornamental birds, as well as for consumers and the environment. The Authority also concluded that the solid water-soluble formulation of the additive is considered not irritant to skin or eyes. Due to the proteinaceous nature of the active agent, both solid and solid water-soluble formulations of the additive are considered respiratory sensitisers. The Authority could not conclude on the potential of the solid formulation of the additive to be irritant to skin and eyes or on the potential of both formulations of the additive to cause skin sensitisation. Furthermore, it concluded that the use of *Enterococcus lactis* NCIMB 11181 is compatible with the coccidiostats monensin sodium and decoquinate. After the assessment of newly submitted data by

[1] OJ L 268, 18.10.2003, p. 29. ELI: http://data.europa.eu/eli/reg/2003/1831/oj.

[2] *EFSA Journal*. 2024;22:e8623. https://doi.org/10.2903/j.efsa.2024.8623.

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the applicant, the Authority concluded in its opinion of 16 September 2025[3] that the additive has the potential to be efficacious as a zootechnical additive for chickens for fattening when supplemented at 3×10^{10} CFU/kg complete feed and in water for drinking at 1.5×10^{10} CFU/L. The conclusion in chickens for fattening is extended to chickens reared for laying and extrapolated to all poultry for fattening, all poultry reared for laying and ornamental birds. The Authority did not consider that there is a need for specific requirements of post-market monitoring.

(5) The Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in a previous assessment concerning another application for the authorisation of the same additive and verified by the Authority in its opinion of 1 February 2012[4] are valid and applicable for the current application. In accordance with Article 5(4), point (a), of Commission Regulation (EC) No 378/2005[5], an evaluation report of the Reference Laboratory was therefore not required.

(6) In view of the above, the Commission considers that the preparation of *Enterococcus lactis* NCIMB 11181 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that preparation should be authorised for poultry for fattening and reared for laying or reproduction and ornamental birds. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1
Authorisation

The preparation specified in the Annex, belonging to the additive category ‘zootechnical additives’ and to the functional group ‘gut flora stabilisers’, is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2
Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union.*

This Regulation shall be binding in its entirety and directly applicable in all Member States.

[3] *EFSA Journal.* 2025;23:e9680. https://doi.org/10.2903/j.efsa.2025.9680.
[4] EFSA Journal 2012;10(2):2574. https://doi.org/10.2903/j.efsa.2012.2574.
[5] Commission Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives (OJ L 59, 5.3.2005, p. 8; ELI: http://data.europa.eu/eli/reg/2005/378/oj).

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Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN